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09/764,560	01/17/2001	Robert Wayne Glenn JR.	8392	6902

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 05/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/764,560

Applicant(s)

GLENN ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 10-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-21 and 24-30 is/are rejected.
- 7) ☒ Claim(s) 22 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- |                                                                                              |                                                                             |
|----------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:                                          |

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### DETAILED ACTION

Receipt of request for extension of time and amendment B, dated 1-13-03 is acknowledged.

Claims 7-9 have been deleted. Claims 1-6 and 10-30 are pending.

The following is a new rejection applied to the pending claims:

#### *Claim Rejections - 35 USC § 112*

1. Claims 1-6 and 10-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Instant claim 1 recites "a reactive agent selected from the group consisting of an electrophilic group selected from the group consisting of halotriazine,... or mixtures thereof or a protected thiols reactive group", which is indefinite because is it the reactive group that forms the reactive agent or is it a compound that contains an electrophilic or a thiol protective group forms the reactive agent. If the latter is true, it is suggested that the claims recite the same. Further, if the thiol reactive group is protected, then how is the thiol group reactive or active functionally? Specification states that the reactive agent is a compound. If so, how can a compound be selected from electrophilic groups or thiol protected groups? The claims should state a reactive agent is selected from compounds consisting the above groups. A clarification and appropriate correction is requested.

2. Claim 4 recites the limitation "nucleophilic groups" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Appropriate correction is requested.

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### *Claim Objections*

3. Claim 10 is objected to because of the following informalities: Claim 10 is dependent on claim 9, which has been canceled by amendment B. Appropriate correction is required.

### *Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-6 and 10-30 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-22 of copending Application No. 09/799,185. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant treatment composition includes all the components i.e., an aqueous phase, a discontinuous phase containing a reactive component and an immiscible solvent for the reactive component, recited in the copending claims. Further, copending claims also recite that the composition is in the form of an emulsion also contains the

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same reactive agents as claimed in the instant application. Accordingly, it would have been obvious for a skilled artisan at the time of the instant invention to prepare the instant treatment composition from the composition of the copending application because the copending application (on page 40) specifically states that the surfactants of the discontinuous phase forms a layer between the primary emulsion and the external aqueous phase.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 1-6 and 10-30 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 09/764,561. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant treatment composition includes all the components i.e., an aqueous phase, a discontinuous phase containing a reactive component, surfactant and an immiscible solvent for the reactive component, recited in the copending claims. Further, copending claims also recite the same reactive agents as claimed in the instant application. Although copending claims do not explicitly state the formation of a bi-layered structures by the surfactant the copending claims are generic to the instant surfactants (see page 16 of the copending application), which is also recited in the instant claims and is capable of forming bi-layers. Accordingly, it would have been obvious for a skilled artisan at the time of the instant invention to prepare the instant treatment composition from the composition of the copending application because the copending application (on page 40) specifically states that the

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surfactants of the discontinuous phase forms a layer between the primary emulsion and the external aqueous phase.

6. Claims 1-6 and 10-30 are directed to an invention not patentably distinct from claims 1-22 of commonly assigned 09/799,185 and claims 1-42 of commonly assigned 09/764,561.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 09/799,185 and 09/764,561, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

7. Claims 1-6 and 10-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over 09/799,185 and 09/764,561.

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The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Specifically, both the copending applications describe a treatment composition containing the reactive agents having the same reactive groups, aqueous continuous phase, surfactants and application of the compositions to hair or other substrates containing an amino acid base that reacts with the reactive agent. Therefore, it would have been obvious for a skilled artisan at the time of the instant invention to prepare the instant treatment composition from the composition of the copending application because the copending applications teach that the surfactants of the discontinuous phase forms a layer between the primary emulsion and the external aqueous phase.

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**In response to the amendment B, examiner has withdrawn the rejection of claims 1-6, 8, 11-21 and 24-30 as being obvious over Zysmann et al. However, in view of the amendment to claim 1, the following rejection (previously applied to claims 7, 9, 10, 22 and 23) is applied to the instant claims.**

8. Claims 1-6 and 10-21 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,362,494 to Zysman et al (hereafter Zysman) in view of US 5,525,332 to Gough et al (hereafter Gough).

Zysman teaches cosmetic, dermo-pharmaceutical compositions containing non-ionic and ionic amphiphilic surfactants, which form vesicles. Zysman teaches oil-in-water and water-in-oil compositions in which the amphiphilic surfactants are employed along with other surfactants (col. 3, lines 53-65). The amphiphilic surfactants of Zysman include natural and synthetic phospholipids (col. 5, lines 26-37). Zysman teaches that the vesicles are dispersed in an aqueous phase, which contains water immiscible solvents to stabilize vesicles, which include oils, hydrocarbon compounds, silicones etc (col. 12, lines 25-57). Further, the water immiscible solvent contains lipophilic active substances, which read on the instant reactive components. The surfactants of instant claim 1 read on the amphiphilic lipids of Zysman and the dispersion of vesicles in the aqueous phase (taught y Zysman) is nothing but a bi-layer emulsion, as claimed.

Zysman teaches addition of active agents in the composition to either encapsulated water phase or continuous water phase or the lipid phase, depending on the solubility of the active agent used and further suggests a number of skin and hair care active agents (col. 7, lines 28-60)



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and in particular, compounds that are suitable for treating hair loss, for hair dyes, bleaching and permanent waving of hair (such as N-acetylcysteamine) (col. 11, lines 50-68). Examiner notes that N-acetylcysteamine of Zysman read on the instant reactive component (claim 1) and in particular, nucleophilic reactive group (claim 8). Further, N-acetylcysteamine also meets the requirement of being covalently reactive with an amino acid based substrate because instant specification describes cysteamine derivatives as reactive component and hair keratin as an amino acid base.

With respect to instant combination of cholesterol and quaternary ammonium surfactants, Zysman teaches addition of one more charged lipid to the amphiphilic lipids such as sterols (e.g., cholesterol), quaternary ammonium derivatives etc (col. 7, lines 5-27), so as to impart stability to the vesicles by preventing their flocculation and fusion, as well as increase their encapsulation. Accordingly, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate additional surfactants such as cholesterol or quaternary ammonium compounds in the composition containing aqueous dispersion of vesicles of Zysman because Zysman suggests that the additional charged lipids decrease vesicle permeability, increase their stability, prevent flocculation of the vesicles and finally enhance the encapsulation. With respect to the percentages and ratios of surfactants, Zysman teaches 0.5 to 50% vesicle forming lipids. Further, optimizing the amounts of solvents, active substances and additional lipids such as cholesterol with an expectation to deliver the active substances to the intended site would have been obvious for one of an ordinary skill in the art.

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Zysman fails to teach a reactive agent comprising the claimed electrophilic group in the composition containing aqueous dispersion of lipid vesicles. Zysman suggests incorporating hair-conditioning polymers in the composition.

Gough teaches hair-conditioning composition containing vinyl azolactone and methacryloyl polydimethylsiloxane polymer for imparting conditioning benefit to hair and for improved retention of the conditioning agent for a long time on the hair. The polysiloxane polymer is functionalized with azolactone such that the electrophilic reactive component of azolactone reacts with the nucleophilic reactive sites on the surface of the substrate i.e., hair or keratin fibers (col. 3, col. 4 and col. 7, lines 25-38). Gough also teaches various polymeric materials that can be functionalized with azlactone (col. 6). Further, Gough suggests that the azlactone functionalized materials may be soluble or dispersible in organic solvents such as silicones, hydrocarbons etc., and can be used in solutions or emulsions (col. 7, lines 49-68 and col. 8, lines 1-9). Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate the azolactone functionalized polymers or other cosmetic agents functionalized with azolactone in the aqueous dispersion of Zysman containing amphiphilic lipids in combination with other charged lipids such as cholesterol because Gough teaches that the hair conditioning compounds containing azolactone functionalized polymers are useful in achieving a greater degree of chemical bonding of the cosmetic agent with the substrate due to the electrophilic nature and thus achieve an enhanced degree of hair conditioning and styling for long time (col. 7, lines 25-49).

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9. Claims 1-6, 11-21, 24 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,362,494 to Zysman et al (hereafter Zysman) in view of US 5,087,733 to Deppert et al (hereafter Deppert).

Zysman fails to teach the claimed reactive compounds containing a nucleophilic reactive group, in particular, thiol groups. However, Zysman suggests incorporating hair-conditioning agents in the aqueous dispersions containing amphiphilic vesicles.

Deppert teaches hair-conditioning compositions containing sulfur containing quaternary ammonium compounds such as sulfhydryl, dithio, isothiuronium compounds that react with the anionic charge carried on the keratin of human hair fibers. In particular, after treating with thioglycolic acid (for permanent waving of hair), free mercaptan groups formed due to reduction of thioglycolic acid are remained on the hair fibers. The thiol containing quaternary compounds of Deppert reacts covalently with the free mercaptan groups, thus binding the conditioner to the hair for a longer period of time (col. 8, lines 8-20). Further, Deppert suggest water immiscible solvents such a benzyl alcohol for stabilizing the sulfur containing compounds. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to incorporate the sulfur containing quaternary ammonium compounds such as disulfhydryl, dithiol or diisothiouranium containing quaternary ammonium conditioners of Deppert in the aqueous dispersions containing amphiphilic vesicles of Zysman because the sulfur containing hair conditioners of Deppert interact with the anionic charge of human hair very efficiently i.e., each molecule forms two covalent bonds with sulfhydryl radicals on hair 9col. 9, lines 58-64) and thus bind to the hair through several shampoos (i.e., long lasting effect) (col.1, lines 62-68).

*Response to Arguments*

Applicant's arguments filed on 1-13-03 have been fully considered but they are not persuasive.

Applicants argue that basics of the art of preparing bi-layer structures using glycerol compounds and that preparing the nucleophilic thiols of Zysman are far the easiest in the art. Applicants argue that the currently claimed reactive compounds containing electrophilic groups and the protected thiol groups are highly susceptible to hydrolysis and yet it was surprisingly possible by the present invention to deliver them in a consumer preferred, aqueous, environment. Applicants argue that none of the agents in the general list of the Zysman include the claimed water-sensitive electrophilic or thiol protected groups.

Applicants argue that Gough does not teach the delivery of electrophilic azlactone reactive group via inclusion in water immiscible solvent, which is then incorporated into the bilayer for stability and instead Gough teaches indiscriminate delivery of azalactones in a number of plausible ways.

With respect to the teachings of Deppert, applicants argue that the reference is silent regarding the incorporation of any surfactants, immiscible solvent to form bilayered structures and that Deppert does not teach any requirement for an anhydrous environment for the thiol compounds.

Applicant's arguments are not persuasive because Zysman teaches vehicles for delivering cosmetically active substances that form bi-layered structures and which are used in the form of a dispersion in an aqueous phase (col. 4-5). The dispersions further contain active agents and depending on the solubility the agents are included in the fatty phase or the aqueous phase. Zysman clearly teaches incorporating the water insoluble agents in the water-insoluble or fat-soluble bilayer (col. 7), which is the same as the incorporation of azlactone in an immiscible solvent in the bi-layered structures. While Zysman does not teach azlactone, Zysman teaches that hair-conditioning polymers can also be delivered using their vehicles. Further, Zysman teaches that the aqueous dispersion can contain a dispersion of water-immiscible liquid, which the vesicles stabilize (col. 12). With respect to the teachings of Gough, applicants themselves agree that Gough does teach non-aqueous solutions and organic soluble azalactones, which meet the instant criteria. Accordingly, it would have been obvious for one of an ordinary skill in the art to incorporate the azalactone containing compounds of Gough in the layered vesicles of Zysman because Zysman teaches that the vesicles provide stability for insoluble compounds. Similarly, for the same reasons, it would have been obvious for one of an ordinary skill in the art to incorporate the thiol containing compounds of Deppert, as hair conditioning agents, in the layered vesicles of Zysman because Zysman teaches that the vesicles provide stability for insoluble compounds. Further, incorporating thiol compounds in water immiscible solvents depending on their solubility is within the scope of a skilled artisan at the time of the instant invention.

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*Allowable Subject Matter*

Claim 22 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Further, claim 23, which is dependent upon claim 22, is allowable upon presenting claim 22 in an independent format with all the limitation of the base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
May 7, 2003